

## **900 KAR 1:080. Standards governing scientific misconduct.**

RELATES TO: KRS 194A.050(1), 42 C.F.R. 50.101-50.104

STATUTORY AUTHORITY: KRS 194.050(1)

NECESSITY, FUNCTION, AND CONFORMITY: The promulgation of this administrative regulation is necessary to comply with 42 C.F.R. 50.101 to 50.104 which mandates that the Cabinet for Human Resources establish uniform policies and procedures for investigating and reporting instances of alleged, or apparent, misconduct involving: research or research training, applications for support of research, research training, related research activities, or other activities supported with funds made available under the Public Health Service (PHS) Act. The function of this administrative regulation is to establish a procedure for inquiry, investigation, appeal and disposition of complaints alleging scientific misconduct in activities involving PHS research grants.

Section 1. Definitions. (1) "Inquiry" means information gathering and initial fact finding to determine whether an allegation or apparent instance of misconduct warrants an investigation.

(2) "Investigation" means the formal examination and evaluation of all relevant facts to determine if misconduct has occurred.

(3) "Misconduct", "scientific misconduct", or "misconduct in science" means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgements of data.

(4) "Research" means a systematic investigation designed to develop or contribute to generalizable knowledge and included descriptive and exploratory activities intended to lay the ground work for contributions to knowledge. It does not include investigations designed to support administrative or executive decisions unless the investigation is specifically described by the investigator as scientific.

(5) "Complainant" means an individual, sponsoring agency, or agency person who alleges that scientific misconduct has taken place.

(6) "Respondent" means the individual who is alleged to be guilty of scientific misconduct.

(7) "Sponsoring agency" means the agency which funded the research activities relevant to the alleged scientific misconduct of the respondent.

(8) "Secretary" is defined in KRS 194.020.

(9) "Cabinet" is defined in KRS 194.010.

(10) "OSI" means the Office of Scientific Integrity of the National Institutes of Health of the Department for Health and Human Services.

(11) "PHS" means the U.S. Public Health Service.

(12) "HHS" means the U.S. Department for Health and Human Services.

(13) "Act" means the Public Health Service Act, as amended, (42 U.S.C. 201 et seq.).

Section 2. Applicability of this Administrative Regulation. This administrative regulation applies only to the investigating and reporting of instances of alleged, or apparent, misconduct involving: research or research training, applications for support of research, research training, related research activities, or other activities supported with funds made available under the Public Health Service (PHS) Act.

Section 3. Initial Inquiry. (1) Following receipt of a complaint alleging scientific misconduct involving research or research training, applications for support of research or research training, or related research activities that are supported with funds made available under the Act, the secretary shall:

(a) Consult with the appropriate commissioner or office head; and

(b) Appoint a complaint review team, composed of a minimum of three (3) members, to conduct

an inquiry into an allegation of scientific misconduct.

(2) Members of the complaint review team shall:

- (a) Have no real or apparent conflicts of interest bearing on the case in question;
- (b) Have sufficient training and expertise to understand and to apply the concepts of "science" and "misconduct" to the research study within which misconduct has been alleged; and
- (c) Conduct the inquiry in an unbiased and confidential manner.

(3) Except as provided in subsection (4) of this section, upon initiation of an inquiry the complaint review team shall:

- (a) Examine the basis of the complaint;
- (b) Notify the respondent of the:
  - 1. Substance of the complaint allegations;
  - 2. Procedure for inquiry, investigations and appeal; and
  - 3. Respondent's obligation to cooperate and provide materials or information necessary to conduct the inquiry;
- (c) Prepare a written report, as specified in Section 2(9) of this administrative regulation; and
- (d) Forward the report to the secretary within sixty (60) days or less from the date of the complaint referral.

(4)(a) The complaint review team may request that the secretary grant an extension of the inquiry beyond sixty (60) days.

(b) A request for an extension shall be in writing, and shall:

- 1. State the reasons for the delay and why an extension is necessary; and
- 2. Describe the progress of the inquiry to date.

(c) The secretary shall grant an extension if he determines that circumstances warrant an extension.

(d) If an extension is granted by the secretary, the complaint review team shall notify the respondent, complainant, and sponsoring agency of the extension.

(5) The complaint review team shall immediately notify the secretary if it determines that any of the following circumstances appear to exist:

- (a) An immediate health hazard;
- (b) An immediate need to protect public funds or equipment;
- (c) An immediate need to protect the interests of the persons making the allegations or the individual subject to the allegations or his coinvestigators or associates, if any;
- (d) A probability that the alleged incident will be reported publicly; and
- (e) A reasonable indication of possible criminal activity in a Public Health Services Grant. In this instance, the secretary shall inform the OSI within twenty-four (24) hours of obtaining such information.

(6) The Director of OSI shall be notified when:

- (a) A formal investigation is warranted; or
- (b) An inquiry is terminated before its conclusion.

(7) An agency or institution shall securely retain detailed documentation of the inquiry for a period of three (3) years for the purpose of later assessment of the reasons for which an investigation was not warranted.

(8)(a) During and upon completion of the inquiry, the complaint review team shall:

- 1. Protect the privacy of those persons, who in good faith, report alleged misconduct; and
- 2. Afford the respondent confidential treatment to the maximum extent possible.

(b) A respondent shall have the right to comment upon the:

- 1. Allegations;
- 2. Inquiry findings; and
- 3. Subsequent investigation.

(9)(a) The complaint review team shall submit a written report to the secretary within sixty (60) days of the date of referral.

(b) The report shall include a:

1. Description of evidence reviewed;
2. Summary of the names and statements of persons interviewed; and
3. Inquiry conclusions and recommendations.

(10) Upon the completion of the inquiry, the secretary shall provide:

(a) The respondent with a copy of the inquiry report; and

(b) A written notice to the respondent and complainant of his determination to:

1. Conduct a formal investigation; or
2. End the inquiry, if the allegation is unsupported by the facts, and it has been determined that no further formal action will be taken.

(11) The cabinet shall:

(a) Maintain documentation of inquiries in a secure manner for a period of at least three (3) years after the termination of the inquiry; and

(b) Upon request, make the documentation available to authorized Health and Human Services personnel.

Section 4. Investigation Notification. (1) The secretary shall undertake an investigation if the findings from the inquiry provide a sufficient basis for conducting an investigation.

(2) If the secretary determines that an investigation is warranted, the secretary shall:

(a) Commence the investigation within thirty (30) days of completion of the inquiry;

(b) Provide written notification to the:

1. Director of the OSI, on or before the date the investigation commences;
2. Complainant;
3. Respondent; and
4. Sponsoring agency.

(3) The notification to OSI shall include:

(a) The name of the respondent;

(b) A statement of the nature of the allegation(s); and

(c) The public health service application or grant number involved.

(4)(a) Information provided to OSI shall:

1. Be held in confidence to the extent permitted by law; and
2. Not be disclosed as part of the federal peer review and advisory committee review process.

(b) The information may be used by the Secretary of Health and Human Services in making decisions about the award or continuation of funding.

(5) The respondent shall have the right to:

(a) Respond to the allegation, inquiry and report findings; and

(b) Be represented by legal counsel.

Section 5. Investigation Procedure. (1) The investigation shall be conducted by:

(a) An investigatory team appointed by the secretary taking precautions to avoid real or apparent conflicts or interest on the part of those involved in the investigation; and

(b) A legal representative of the Department of Law.

(2) The secretary may choose to appoint additional investigation team members who may provide expertise necessary to conduct a thorough investigation.

(3) The investigation of the alleged incident of scientific misconduct shall include at least an:

(a) Examination of all documentation gathered during and subsequent to the inquiry;

(b) Related research data and proposals;

- (c) Related publications;
- (d) Related correspondence;
- (e) Memoranda of any related telephone calls; and
- (f) Interviews of all individuals involved, including the complainant and respondent.
- (4) Complete summaries of all interviews shall be:
  - (a) Prepared and provided to the interviewed party for comment or revision; and
  - (b) Included as part of the investigatory file.
- (5)(a) The investigation team shall submit the information specified in Section 4(9) of this administrative regulation to the secretary within 120 days from the commencement of the investigation.
  - (b) This period shall include:
    - 1. Conducting the investigation;
    - 2. Making the report available to the respondent for comment; and
    - 3. Submitting the report to OSI.
- (6)(a) If an investigation cannot be completed within 120 days, the investigatory team shall submit a written request to the secretary for an extension of time.
  - (b) The request shall contain an:
    - 1. Explanation of the reason for the delay;
    - 2. Interim report of the progress made; and
    - 3. Estimate of time required for completion.
  - (c) If the secretary agrees with the request for an extension, he shall resubmit a request for an extension of the investigation to OSI. The request shall contain the items specified in paragraph (b) of this section.
- (7)(a) If an extension is granted, the cabinet shall file periodic progress reports with the OSI.
- (b) If satisfactory progress, in the investigation, has not been made by the cabinet, the OSI may undertake an investigation of its own.
- (8) If it is determined by the investigation team that additional information, discovered during the investigation process, justifies broadening the scope of the investigation beyond the initial allegations, the team shall notify the:
  - (a) Secretary;
  - (b) OSI; and
  - (c) Respondent.
- (9) Upon completion of the investigation, the investigation team shall submit a final written report to the secretary. The report shall include:
  - (a) A description of the procedures under which the investigation was conducted;
  - (b) Names and titles of persons interviewed;
  - (c) How information was obtained relevant to the investigation;
  - (d) Supporting documentation;
  - (e) Basis for findings;
  - (f) Findings, including the actual text or an accurate summary of the statements of the respondent; and
  - (g) Recommended disciplinary actions.
- (10) Upon receipt of the final report, the secretary shall make a finding:
  - (a) Of misconduct and the disciplinary action to be taken by the cabinet;
  - (b) That no culpable conduct was committed, but serious scientific errors were discovered; or
  - (c) That no fraud, misconduct or serious scientific error was committed.
- (11) The secretary shall forward written notification of the findings and a copy of the final report to the:
  - (a) Director of OSI;
  - (b) Respondent; and

(c) Sponsoring agency.

Section 6. Inquiry or Investigation Termination. If the cabinet intends to terminate an inquiry or investigation for any reason without completing the requirements of this administrative regulation, a report shall be filed to OSI stating the:

- (1) Intention to terminate; and
- (2) A description of the reasons for termination.

Section 7. Investigation Findings. (1) Documents, proceedings, findings and reports pertaining to the inquiry, investigation and final disposition shall be:

- (a) Maintained as confidential; and
- (b) Retained by the agency in a secure file for a period of three (3) years.

(2) If confidentiality is breached, the secretary shall take reasonable steps to minimize damage to the respondent's reputation that may result from inaccurate reports.

(3) The secretary may make a determination that no formal action will be taken, other than informing all involved parties if:

- (a) An allegation is found to be unsupported; and
- (b) Has been submitted in good faith.

(4) The secretary shall:

(a) Pending completion of the inquiry or investigation, have the authority to take interim disciplinary actions as he deems necessary to promote the integrity of:

1. Scientific research;
2. Funding;
3. Documentation; and
4. The reputations of all parties involved in the inquiry and investigation;

(b) Implement measures to:

1. Protect, to the maximum extent possible, the privacy of those, who in good faith, report apparent misconduct; and

2. Prevent retaliatory action against the complainant.

(5) If the respondent resigns from employment, the cabinet shall ensure that the investigation is completed.

Section 8. Appeal of the Finding of the Final Report. (1) If the respondent is an employee of the Cabinet for Human Resources, then the secretary may use the disciplinary powers available to him as secretary and any appeals should be made to the Personnel Board as provided for in KRS 18A.095.

(2) If the respondent is not an employee of the Cabinet for Human Resources, then the secretary may use those disciplinary options and appeals that shall be built into the grant or contract, funding the research involved in the allegation of misconduct.

(3) After the time limit for an appeal expires or after all appeals have been resolved, the secretary may at his discretion, give notification to:

- (a) Sponsoring agencies, funding sources;
- (b) Coauthors, coinvestigators, collaborators;
- (c) Editors of journals in which fraudulent research was published;
- (d) State professional licensing boards;
- (e) Editors of journals or other publication, other institutions, sponsoring agencies, funding sources with which the respondent has been affiliated;
- (f) Professional societies; and
- (g) Where appropriate, criminal authorities.

(4) The process for appealing any actions imposed by the U.S. Department of Health and Human Services shall be through the appeals process set up by the U.S. Department of Health and Human Services for this purpose. (20 Ky.R. 2943; eff. 6-2-94.)